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Remarks:

Regarding the rejection of claim 7 under 35 USC 112:

The claim is corrected as suggested; the undersigned thanks the Examiner for the helpful suggestion.

Regarding the rejection of claims 1-7 under 35 USC 102 in view of WO 00/42992 to Chen et al. (hereinafter simply "Chen"):

The applicants respectfully traverse the Examiner's ground of rejection over the Chen reference, particularly in view of the amended claims.

Prior to more specifically discussing the Examiner's rejection as to "obviousness" over the prior art, the undersigned reminds the Examiner that the determination of obviousness under § 103(a) requires consideration of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 [148 USPQ 459] (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368, 67 USPQ2d 1649, 1653 (Fed. Cir. 2003). There must be some suggestion, teaching, or motivation arising from what the prior art would have taught a person of ordinary skill in the field of the invention to make the proposed changes to the reference. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). But see also *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D 1385 (U.S. 2007).

A methodology for the analysis of obviousness was set out in *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000) A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the

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invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."

It must also be shown that one having ordinary skill in the art would reasonably have expected any proposed changes to a prior art reference would have been successful. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

Whereas the Examiner asserts that the applicant's invention is obvious over the prior art Chen reference, the applicant strongly disagrees particularly in view of the currently presented claims. Specifically, the claims have been amended to incorporate the features into claim 1 which affects the scope of this independent claims as well as all dependent claims.

In contrast to the prior art, the applicant's claims as currently amended in this paper are directed to compositions comprising about 8 wt% acid.

Applicant's specification describes the problem involved in the formulation of compositions comprising such a high concentration of acids as is recited by the applicant in their specification, the following except from applicant's specification at pages 2 and 3 which reads as follows:

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30 However, there are considerable technical challenges associated with incorporating food acids into edible films. In particular, applicant found that a film's mechanical strength was compromised by adding food acid to the film. It was also observed that the films displayed poor hygroscopic stability making them difficult to manufacture and store, and unattractive to consumers. For example, in some cases the films when placed together tend to stick together to form a gum.

It is highly desirable to provide films that can deliver a tartness or sourness and mouth-watering effect and which are mechanically strong and hygroscopically stable.

5 The applicant has now surprisingly found that by combining certain types of film-forming polymers it is possible to form edible films that rapidly dissolve or disintegrate and disperse in the mouth and which solve the problems referred to above.

10 Accordingly, the invention provides in a first aspect an edible film for delivering an active agent to the oral cavity comprising a water-dispersible film-forming material selected from a cellulose ether and a starch, and a food acid.

20 These food acids, are preferably employed in edible film formulations at levels of at least about 8% by weight based on the dry weight of the edible film composition, more preferably from about 8% to about 25% by weight. Dry weight according to the present invention refers to the weight of all of the edible film composition components without added water. The above-mentioned levels of food acids are preferred in order to give a desirable tartness or sourness impression and to achieve a desirable mouth-watering effect. Whereas, it may be possible to incorporate lower amounts of acid into the films and thereby avoid any instability problems associated with the films, one cannot reliably achieve the desirable mouth-sensations aforementioned.

In short, if food acids were to be incorporated in formulations in higher concentrations, in particular of at least about 8% of acid, instability problems could result, unless choosing the composition of claim 1.

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Chen's specification is unduly vague with regard to the utility or function of acids in their composition, namely Chen's disclosure relevant disclosure (at pages 14 and 15) reads as follows:

- In addition to hydrocolloids and the active agents, the films may contain any or
- 5 all of the following ingredients: emulsifying agents, solubilizing agents, wetting agents, taste modifying agents, plasticizers, active agents, water soluble inert fillers, preservatives, buffering agents, coloring agents, and stabilizers. In a preferred embodiment, the percentage dry weight concentration of at least single ingredients incorporated in a film in each of the following categories is as follows: emulsifying
- 10 agent (0.1%-10%), plasticizer (0.5-20%), active agents (0.01-75%), taste modifying agents (0.1-10%), coloring agents (0.01-5%), water soluble inert fillers (0.5-50%), preservatives (0.01-10%), buffering agents (0.1-10%) and stabilizers (0.01-5%).

Chen's film formulation may contain various of the above agents, including one or more of the following hydrocolloids:

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In embodiments of the invention, the hydrocolloid may be a water soluble non-gelling (at room temperature) natural polysaccharide or derivatives including pectin and derivatives, guar gum arabic, tragacanth gum, xanthan gum, gellan sodium salt, 15 propyleneglycol alginate, starches (amylose, amylopectin), modified starches, hydroxyethyl starch, pullulan, carboxymethyl starch, gum ghatti, okra gum, karaya gum, dextrans, dextrans and maltodextrins, konjac, acemannan from *aloe*, locust bean gum, tara gum, quince seed gum, fenugreek seed gum, scleroglucan, gum arabic, psyllium seed gum, tamarind gum, oat gum, quince seed gum, carrageenans, scleroglucan, 20 succinoglucan, larch arabinogalactan, flaxseed gum, chondroitin sulfates, hyaluronic acid, curdlan, chitosan, deacetylated konjac, and *rhizobium* gum.

In embodiments of the invention, the hydrocolloid may be a water soluble non-gelling polypeptide or protein exemplified by gelatins, albumins, milk proteins, soy protein, and whey proteins. The hydrocolloid may further be selected from a group of 25 synthetic hydrocolloids exemplified by any of the following: polyethylene-imine, hydroxyethyl cellulose, sodium carboxymethyl cellulose, carboxymethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, methyl cellulose, ethyl cellulose, polyacrylic acids, low molecular weight polyacrylamides and their sodium salts (carbomers), polyvinylpyrrolidone, polyethylene glycols, polyethylene oxides, 30 polyvinyl alcohols, pluronics, tetronics, and other block co-polymers, carboxyvinyl polymers, and colloidal silicon dioxide. A preferred embodiment of the invention

With regard acids, again Chen's disclosure is very general and vague, at best disclosing buffering agents that include both acidulants and alkalizing agents such as various carbonates recited by Chen (at page 11), which are used to keep the pH neutral and *prevent acidification* or alkalization:

Buffering agents include acidulants and alkalizing agents exemplified by citric acid, fumaric acid, lactic acid, tartaric acid, malic acid, as well as sodium citrate, sodium bicarbonate and carbonate, sodium or potassium phosphate and magnesium oxide.

20 Coloring agents may include FD & C coloring agents, natural coloring agents,

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It is of no small significance to note that Chen's possible acidulants are necessarily present in Chen's compositions in only minor amounts, as their use in maintaining the pH of Chen's compositions is in stark contrast to the technical function of these materials are taught only in the present application, where high acid concentrations that induce a clearly acidic mouthwatering effect are used.

Nowhere did Chen realize or even hint at problems when formulating high acid content formulations. Looking at Chen's examples, the reason is apparent: Chen used the *low amounts commonly required for buffering to keep pH neutral*. In each instance (compare tables 1, 3 5 and 7, relevant excerpts below from Chen's specification), the amount of acid was significantly below that of the hydrocolloid, and significantly below 8% dry weight (indeed, it even was below 8% wet weight!):

Table 1: Formulation of quick dissolving films using several different hydrocolloids.

Composition: coating solution %	Ex. 1	Ex. 2	Ex. 3
Pullulan (P-20) w%		17.5	
Methocel E5 w%	21.06		
POLYOX WSR N-10 w%			1.8
Cellulose gum w%			8.1
Citric acid w%	0.7	0.8	
Benzoic acid w%	0.013	0.1	0.01
Water w%	74.42	67.025	85.6

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Table 3: Dry weight percentages for components of Example 1 according to Tables 1 and 2.

Ingredients	Percentage (w/w)
Methocel E5	82.35
Citric acid	2.74
Benzoic acid	0.5

Table 5:

Composition (coating solution)	Ex. 4	Ex. 5	Ex. 6	Ex. 7	Ex. 8
Methocel E5(HPMC)	21.06	21.06	21.06	21.06	21.06
Citric acid	0.7	0.7	0.7	0.7	0.7
Benzoic acid	0.013	0.013	0.013	0.013	0.013
Water	74.43	73.03	71.51	70.72	72.94

Table 7: Composition of the Sildenafil film (%wet base)

Composition	Percentage
Methocel E15	4.59
Benzoic acid	0.0045

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Water	55
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Thus, Chen's compositions nowhere address any of the technical issues which are addressed and overcome by the applicant's present invention, as none of Chen's compositions include the same constituents, in the same amount as presently claimed by the applicant. This is in stark contrast to the successful compositions which the present applicants have provided in their patent application, which allows for the incorporation of the high amounts of food acid as currently claimed, viz., of at least about 8%. An even greater amount is exemplified by the applicants in their patent application, e.g. Example 1 of the present application, showing the successful incorporation of almost 15% acid based on dry weight, which is reproduced here for convenient reference:

	Wet Wt	Dry Wt
Deionised Water	582.7	
Pure Coat 792 Modified Starch	20	20
HPMC	35	35
Malic acid	50	50
TOTAL	1000	335.4

Notably, Chen does not address nor show the incorporation of higher concentrations of acid as claimed, instead, Chen discloses a multitude of formulations that may contain either acidulants or alkalizing agents *as buffering agents*, i.e. in contrast to the subject matter described in the present application, to achieve a *neutral* pH, rather than an acidic one.

As can be readily seen from inspection of the compositions exemplified by Chen, and the compositions provided by the present applicant and now claimed, the presently claimed invention requires *at least 10 times the amount of the acid* which is present in Chen's examples, which is a significant distinction over the prior art Chen compositions.

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Accordingly, reconsideration of and withdrawal of the current rejection of the claims is solicited.

Regarding the rejection of claims 8-11 under 35 USC 103a in view of WO 00/42992 to Chen et al. (hereinafter simply "Chen") and Dictionary.com definition of wafer:

In view of the amendments to the claims, and further in view of the remarks entered above concerning claims 1-7, as the applicant believes these claims are patentable, by default all dependent claims, including claims 8-11, are believed to be patentable over the prior art Chen reference for at least the reasons stated above. Accordingly, reconsideration of and withdrawal of the instant rejection is solicited.

PETITION FOR A TWO-MONTH EXTENSION OF TIME

The applicants respectfully petition for a two-month extension of time in order to permit for the timely entry of this paper. The Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263 with respect to this petition.

CONDITIONAL AUTHORIZATION FOR FEES

Should any further fee be required by the Commissioner in order to permit the timely entry of this paper, the Commissioner is authorized to charge any such fee to Deposit Account No. 14-1263.

Should the Examiner in charge of this application believe that telephonic communication with the undersigned representative would meaningfully advance the prosecution of this application towards allowance, the Examiner is invited to contact the undersigned at their earliest convenience.

JAN 21 2009

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Respectfully Submitted;



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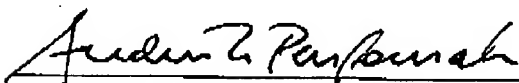
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20 Jan 2009

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Andrew N. Parfomak

20 Jan 2009

Date

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